Stanley W. Parry, Esq.
Nevada Bar No. 1417
Edward Chang, Esq.
Nevada Bar No. 11783
BALLARD SPAHR LLP
100 North City Parkway, Suite 1750
Las Vegas, Nevada 89106-4617
Telephone: (702) 471-7000
Facsimile: (702) 471-7070
E-mail: parrys@ballardspahr.com
E-mail: change@ballardspahr.com

Stephen J. Kastenberg, Esq.
(admitted pro hac vice)
Jason A. Leckerman, Esq.
(admitted pro hac vice)
Jessica M. Anthony, Esq.
(admitted pro hac vice)
BALLARD SPAHR LLP
1735 Market Street, 51st Floor
Philadelphia, Pennsylvania 19103
Telephone: (215) 665-8500
Facsimile: (215) 864-8999
E-mail: kastenberg@ballardspahr.com
E-mail: leckermanj@ballardspahr.com
E-mail: anthonyj@ballardspahr.com

Attorneys for Defendant
GlaxoSmithKline LLC

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

THE VACCINE CENTER LLC, d/b/a THE VACCINE CENTER AND TRAVEL MEDICINE CLINIC, a Nevada limited liability company,

Plaintiff,

vs.

GLAXOSMITHKLINE LLC, a Delaware limited liability company; APEXUS, INC., a Delaware corporation; SOUTHERN NEVADA HEALTH DISTRICT; DOES I – X and ROE CORPORATIONS I – X, inclusive,

Defendants.

Case No. 2:12-cv-01849-JCM-NJK

EXHIBIT 1-A FILED UNDER SEAL PURSUANT TO COURT ORDER DATED FEBRUARY 25, 2013

DEFENDANT GLAXOSMITHKLINE'S MOTION FOR SUMMARY JUDGMENT

(Oral Argument Requested)

TABLE OF CONTENTS

Page

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Rule 56-1, Defendant GlaxoSmithKline LLC ("GSK") requests that the Court grant summary judgment in its favor and against plaintiff, The Vaccine Center, a for profit business owned and operated by Jonathan Baktari, M.D. This Motion is made and based on the following memorandum of points and authorities, the declaration of Edward Chang attached hereto as Exhibit 1, the declaration of Bonnie Sorenson attached hereto as Exhibit 2, the attached exhibits, the papers and pleadings on file, and any oral argument the Court may deem necessary. In addition, in order to avoid repetitious briefing to the Court, GSK joins the Motion for Summary Judgment filed by Defendant Apexus, Inc. ("Apexus").

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

This lawsuit arises from The Vaccine Center's complaint that its for-profit enterprise is less profitable because it supposedly loses vaccinations (and, thus, sales) to a public health district that inoculates members of the public with vaccines purchased from GSK through a federally conceived and directed program. Specifically, The Vaccine Center's Amended Complaint alleges that GSK's discounted sales of vaccines to the Southern Nevada Health District ("SNHD"), made pursuant to the congressionally enacted Prime Vendor Program, constitute price discrimination in violation of the Robinson-Patman Act.

The premise of plaintiff's claim is simple: as a for-profit vaccine and travel medicine provider, federal statute prevents it from purchasing vaccines under the Prime Vendor Program; therefore, it does not have access to the same prices available to SNHD, which qualifies as an entity able to purchase as part of the Prime Vendor Program. SNHD is a covered entity for that Program pursuant to 42 U.S.C. § 256(b)(a)(4), which defines the eligibility of health care organizations, most commonly based on receiving federal grants. As a statutorily created public health

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

organization, SNHD provides, among other services, immunizations to members of the community to prevent the spread of communicable disease.

The misguided nature of the claim against GSK virtually leaps off the page. According to plaintiff, by participating in a federal program to sell vaccines at discounts to a statutorily created public health organization, enabling it to better fulfill its public health mission by vaccinating a larger segment of the public (at lower costs to it and consumers), GSK owes a for-profit vaccine center punitive treble damages for violating the federal antitrust laws. Not surprisingly, the law does not permit a federal program participant like GSK to be whipsawed in this way. Instead, any grievance The Vaccine Center may have is not one properly aimed at GSK or any other defendant. The federal government, acting through the Office of Pharmacy Affairs of the Health Resources Services Administration (an agency of the U.S. Department of Health and Human Services), directed that vaccines be included in the Prime Vendor Program; any challenge the government's decision do so should be directed at it, not private parties.[1] As a result, GSK, acting with the endorsement and consent of the government, is immune from antitrust liability for its sale of vaccines to SNHD pursuant to the Prime Vendor Program.

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

[1] Plaintiff is in effect challenging the scope of HRSA's discretion. Such a challenge should be made directly against the United States under the Administrative Procedure Act. See Cal. ex rel. Imperial County Air Pollution Control Dist. v. United States Dep't of Interior, No. 09-2233, 2012 U.S. Dist. LEXIS 49020, at *14 (S.D. Cal. Apr. 6, 2012) ("The APA provides 'the sole means for testing the legality of federal agency action' when an agency is alleged to have violated a federal law that confers no private right of action or whose citizen suit provision is not applicable to the particular dispute.") (citations omitted); see also Glacier Park Found. v. Watt, 663 F.2d 882, 885 (9th Cir. 1981) ("A plaintiff need not establish a private right of action under a statute before it may sue under the APA."). Similarly aggrieved parties regularly choose this path. See, e.g., Managed Pharm. Care v. Douglas, No. 12-55067, 2012 U.S. App. LEXIS 25478 (9th Cir. Dec. 13, 2012) (suit under APA brought against HHS by providers of California Medicaid services regarding Secretary's interpretation of Medicaid statute and approval of State's reduction of reimbursement rates to providers); Pinnacle Health Hosps. v. Sebelius, 681 F.3d 424, 426 (D.C. Cir. 2012) (hospitals brought suit pursuant to APA against HHS for denial of Medicare reimbursement claim for the losses the hospitals sustained during a consolidation).

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

Moreover, even if GSK's conduct were not immune, the federal Nonprofit Institutions Act ("NPIA") exempts the vaccine sales to SNHD. As a charitable institution for purposes of the NPIA, purchases of supplies for SNHD's "own use" do not fall within the Robinson-Patman Act. Whether items are for an entity's "own use" asks if the use promotes the "intended institutional operation" of the entity.

SNHD operates an immunization program that serves the needs of the community and furthers its goal of protecting and promoting "the health, the environment and well-being of Southern Nevada residents and visitors." As SNHD's Immunization Program Policy Statement explains, "Providing vaccinations is a core public health function, a vital public health tool, and one of the most cost-effective public health-promoting interventions a public health authority . . . can perform."[2] By ordinance, SNHD is charged "[t]o take whatever action that is necessary to control communicable diseases." Improved access to and inoculation by vaccines, which follows from SNHD's efforts in this area, unquestionably advances the goal of improving public health by lowering the public risk of communicable disease. Vaccines used by SNHD in this manner, therefore, fall outside the bounds of the Robinson-Patman Act and cannot be the basis for plaintiff's claims.

II. FACTUAL BACKGROUND

In its motion for summary judgment, Apexus, the federally selected, nonprofit administrator of the Prime Vendor Program, describes the origins and parameters of the program, including its inception from federal statute and the federal agency HRSA. GSK participates in the Prime Vendor Program, selling vaccines to those charitable and public health entities that meet the designated statutory standards for "covered entities." GSK incorporates by reference the procedural and factual

[2] SNHD Immunization Program Policy Statement, available at http://www.southernnevadahealthdistrict.org/download/nursing-iz-policy-statement.pdf.

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

background set forth in Apexus's Motion for Summary Judgment. This section, therefore, focuses on facts not referenced in Apexus's motion

Disease prevention is a fundamental component of public health. Vaccines play a substantial role in disease prevention by reducing the risk of the spread of diseases, benefiting not just those who have been inoculated but the community at large. This is known as "herd immunity" because once immunization levels reach a critical mass, the entire population, even those members who are unvaccinated, benefits.[3] But eradicating disease in this manner relies on widespread vaccination. Nevada, lagging behind the national average for immunization rates, has a particularly pressing need to increase access to vaccines.[4]

SNHD purchases vaccines from GSK for use throughout its immunization program. Included among the immunizations provided are: vaccines for children, seasonal flu vaccines, pneumonia vaccines for the elderly, vaccines for travelers, and vaccines for college students. In addition, SNHD administers routine vaccines on an age-appropriate basis in its clinics.[5] Plaintiff's complaint focuses only on vaccines purchased by SNHD pursuant to the Prime Vendor Program.

The Vaccine Center has purchased four vaccines from GSK: Boostrix, Havrix, Engerix, and Twinrix, adult vaccines for, respectively, tetanus/diphtheria/pertussis, hepatitis A, hepatitis B, and a combination of both hepatitis A and B. Diphtheria and pertussis are both respiratory diseases that, before widespread vaccination, posed serious health risks, particularly to children.[6] Tetanus is a life-threatening

---

[3] Community Immunity, vaccines.gov, available at http://www.vaccines.gov/basics/protection/.

[4] Nevada State Immunization Program, Legislative Briefing, March 2011, available at http://health.nv.gov/BudgetDocuments/2012-2013/NevadaStateImmunizationProgram-LegislativeBriefing.pdf.

[5] SNHD formerly entered into contracts with local employers to provide vaccinations to employees.

[6] Centers for Disease Control and Prevention, Pertussis (Whooping Cough), available at http://www.cdc.gov/pertussis/; Centers for Disease Control and Prevention, Diphtheria Vaccination, available at http://www.cdc.gov/vaccines/vpd-vac/diphtheria/default.htm.

disease, transmitted typically through contaminated soil, dust, or manure entering through breaks in the skin.[7] Full vaccination is by far the best prevention of the diseases.[8] Immunization for tetanus, diphtheria, and pertussis is commonly given as a combination vaccine, and a booster is recommended for adults every ten years. As plaintiff acknowledges, vaccines for hepatitis A and hepatitis B are two of the most widely administered in the country. (Am. Compl. at ¶ 43.) Nevertheless, hepatitis A and B present serious public health challenges. Hepatitis is the leading cause of liver cancer in the United States.[9] Each year there are 51,000 new cases of hepatitis B, 95 percent of which are adults.[10] And 15 percent of people afflicted with hepatitis A are hospitalized each year.[11] The U.S. Departments of Health and Human Services, Housing and Urban Development, Justice, and Veterans Affairs issued an Action Plan for the Prevention, Care, & Treatment of Viral Hepatitis that identifies eliminating transmission of vaccine-preventable viral hepatitis as one of its priority areas.[12] To achieve this goal, increasing access to vaccinations, particularly for vulnerable adults and youth through collaboration with nonfederal entities such as "public health and community stakeholders" is key.[13] Indeed, "success in eliminating transmission of vaccine-preventable viral hepatitis will require the involvement of the many parts of the public health, medical, and research communities, including

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

[7] Centers for Disease Control and Prevention, About Tetanus, available at http://www.cdc.gov/tetanus/about/index.html.

[8] Id.

[9] Centers for Disease Control and Prevention, Viral Hepatitis, available at: http://www.cdc.gov/hepatitis/index.htm.

[10] SNHD, Immunization Program, Adult Vaccines, available at http://www.southernnevadahealthdistrict.org/immunizations/adult-immunizations.php.

[11] Id.

[12] Department of Health & Human Services, Action Plan for Prevention, Care, & Treatment of Viral Hepatitis, available at http://aids.gov/pdf/viral-hepatitis-action-plan.pdf.

[13] Id.

health departments, health care providers . . . pharmaceutical companies and others in the vaccine industry."[14]

SNHD, created by Nevada law, NRS 439.361 et seq., is a public health organization whose geographical boundaries include nearly 70 percent of Nevada's population.[15] It has jurisdiction over all public health matters in the health district. NRS 439.366(2). The mission of the health district reflects its broad statutory authority: "to protect and promote the health, the environment and the well-being of Clark County residents and visitors." It has been specifically tasked by statute with the authority to regulate "the prevention, suppression, and control of any contagious or infectious disease dangerous to the public health." NRS 439.350(2). Pursuant to federal statutory standards, SNHD qualifies as a "covered entity" for purposes of the 340B Drug Pricing Program and its offshoot, the Prime Vendor Program. 42 U.S.C. § 256(b)(a)(4). As a covered entity, SNHD is entitled to purchase discounted products, including vaccines, that are part of the program.

GSK, like many other drug manufacturers, participates in the Prime Vendor Program and, accordingly, negotiates with Apexus, the Prime Vendor, over the products, and prices, GSK offers covered entities that purchase as part of the program.[16] As explained in detail in Apexus's Motion, vaccines were added to the Prime Vendor Program in response to requests from covered entities and at the express consent of HRSA's Office of Pharmacy Affairs, the federal division tasked with administering the program. (Apexus Mot. at IV.D and IV.E.) HRSA's endorsement of the inclusion of vaccines was evidenced in the agency's specific request that applicants for serving as the Prime Vendor address their ability to secure discounts on vaccines. (Id. at IV.E.) Recognizing the importance of

[14] Id.

[15] SNHD, General Information, available at http://www.southernnevadahealthdistrict.org/general-information.php.

[16] Apexus, About Us, available at https://www.340bpvp.com/about-us/.

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

widespread access to vaccines, the agreement between Apexus and GSK currently includes all vaccines sold by GSK. (Pharmacy Supplier Agreement, attached as Exhibit 1-A.) As a qualifying covered entity, SNHD has access to the prices negotiated on the government's behalf by Apexus.

III. ARGUMENT

A. GSK's Conduct Is Immune from Antitrust Scrutiny

The Court should grant summary judgment in favor of GSK because "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986) (citing FED. R. CIV. P. 56(c)). Plaintiff claims that GSK's sales of vaccines to SNHD pursuant to the Prime Vendor Program constitute price discrimination in violation of the Robinson-Patman Act.[17] GSK's sales pursuant to the Prime Vendor Program, however, are immune from antitrust scrutiny.[18] It is axiomatic that the United States government is outside the reach of the antitrust laws. United States v. Cooper Corp., 312 U.S. 600, 614 (1941); Vt. Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765, 790 (2000); Dep't of Water & Power v. Bonneville Power Admin., 759 F.2d 684, 693 (9th Cir. 1985).[19] By extension, "private parties acting in compliance with clearly articulated

[17] Plaintiff initially also asserted that the sales complained of violate the Sherman Act's prohibition on agreements that unreasonably restrain trade, but voluntarily dropped that cause of action in filing its amended complaint. (See Amended Complaint, Docket No. 154.)

[18] The parties agreed, and this Court entered a Stipulated Discovery Plan allowing the parties to address immunity and own use without full discovery. (See Revised Stipulated Discovery Plan and Scheduling Order, Docket No. 152.) Should this action not be resolved on the basis of either of these issues, the parties have reserved the ability to file additional summary judgment motions based on the remaining issues, including those defenses typically available in the antitrust context.

[19] The federal government's sovereign immunity includes purchases made by the government from private entities. This is because the government is not a "purchaser" for purposes of the Robinson-Patman Act. Champaign-Urbana News Agency, Inc. v. J. L. Cummins News Co., 632 F.2d 680, 688 (7th Cir. 1980) ("There is strong evidence in the legislative history that the Robinson-Patman Act Amendments were not intended to include purchases by the federal government. . . .").

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

government policies and programs are immunized from antitrust liability to the same extent as the government entity." IT&E Overseas, Inc., v. RCA Global Commc'ns, Inc., 747 F. Supp. 6, 11 (D.D.C. 1990) (citing S. Motor Carriers Rate Conf. v. United States, 471 U.S. 48, 56-57 (1985)); see Byers v. Intuit, Inc., 600 F.3d 286, 295 (3d Cir. 2010) (finding that a private party is immune when acting "pursuant to a clearly defined policy or program" and at the "direction or consent of the government agency"); Name.Space, Inc. v. Network Solutions, Inc., 202 F.3d 573, 581 (2d Cir. 2000) (same). This is conduct-based antitrust immunity.

When GSK offers discounted prices (negotiated with Apexus acting at the behest of the federal government) to covered entities as part of the Prime Vendor Program, it is acting pursuant to a federal program and with the clearly articulated consent of HRSA, a federal agency. As explained in Apexus's Motion, the inclusion of vaccines as part of the program was at the direction of HRSA's Office of Pharmacy Affairs, the federal agency responsible for administering the program. (Apexus Mot. at IV.E.) Its former Director, Captain James Mitchell, who held the position until 2010, confirms that Apexus received approval to include vaccines in the Prime Vendor Program. (Declaration of J. Mitchell at ¶ 4 attached to Apexus Mot.)

HRSA has continued to consistently endorse vaccines as value-added products within the program. For example, HRSA explained to Congress in 2005 that the Prime Vendor Program has three primary means of increasing value for participating covered entities: 1) negotiating drug prices below the statutorily required 340B ceiling price; 2) entering into favorable distribution agreements with multiple drug wholesalers; and 3) ***providing discounts on other value-added pharmacy products and services***.[20] These value-added pharmacy products includes vaccines. The HRSA

[20] Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency, Hearing Before the S. Comm. on Oversight and Investigations, 109th Cong. 17 (Dec. 15, 2005) (statement of Dennis Williams, Deputy Administrator of HRSA), available at http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/pdf/CHRG-109hhrg30139.pdf (emphasis added). A true and correct copy is attached hereto as Exhibit 3. GSK requests the Court take judicial notice of the information and document, including its (continued...)

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

Request for Proposal by which it selected Apexus to administer the Prime Vendor Program demonstrates as such; it instructed applicants to explain their ability to offer "[l]ower cost products and services not included in the 340B Program (*e.g.*, ***vaccines***, etc.)." (Apexus Mot. at IV.E citing Request for Proposal at p. 47, 190, 193 (emphasis added).) In another report to Congress, HRSA accorded vaccines top billing—listed first among value-added products, when describing the Prime Vendor Program as including "value-added pharmacy products and services such as ***vaccines***, diabetic supplies, pharmacy software, and outpatient pharmacy automation."[21] Thus, the inclusion of vaccines in the Prime Vendor Program was at the direction and full endorsement of HRSA, the federal agency responsible for administering the program. As a result, GSK (like Apexus and SNHD), acting in conformance with the Prime Vendor Program, is immune from antitrust scrutiny for participating in the program. Byers, 600 F.3d at 295.

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

(...continued)
terms, appearing on government websites. See Daniels-Hall v. Nat'l Educ. Ass'n, 629 F.3d 992, 998-99 (9th Cir. 2010) (taking judicial notice of official information posted on a governmental website, the accuracy of which was undisputed); Laborers' Pension Fund v. Blackmore Sewer Constr., Inc., 298 F.3d 600, 607 (7th Cir. 2002) (taking judicial notice of information from official website of the FDIC); Simon v. Bank of Am., N.A., No. 2:10-cv-00300-GMN-LRL, 2010 U.S. Dist. LEXIS 63480, at *15 n.1 (D. Nev. June 23, 2010) ("The Court takes judicial notice of this information provided on the government website."); see also Waterfall Homeowners Ass'n v. Viega, Inc., 283 F.R.D. 571, 574 (D. Nev. 2012) ("Moreover, under Federal Rule of Evidence 201, a court may take judicial notice of matters of public record." (citation and internal quotation marks omitted)); Paralyzed Veterns of Am. v. McPherson, No. C 06-4670 SBA, 2008 U.S. Dist. LEXIS 69542, *17–18 (N.D. Cal. Sept. 9, 2008) (collecting published cases that took judicial notice of information on official government websites); Hightower v. City & County of San Francisco, No. C 12-5841-EMC, 2013 U.S. Dist. LEXIS 12039,* 9–10 (N.D. Cal. Jan. 29, 2013) ("Rule 201 does not bar a court from taking notice of a legislative fact. It simply means that notice of 'legislative facts' is left unregulated by Rule 201. . . . Federal courts have in fact judicially noticed various 'legislative facts'. . . . including determining the validity of administrative regulations." (citing WRIGHT & MILLER, FED. PRAC. & PROC. § 5103.2) (internal quotation marks and alterations omitted)).

[21] Department of Health and Human Services Fiscal Year 2013 Health Resources and Services Administration Justification of Estimates for Appropriations Committees at 297-98, available at http://www.hrsa.gov/about/budget/budgetjustification2013.pdf (emphasis added). A true and correct copy of the relevant excerpt is attached hereto as Exhibit 4. GSK requests the Court take judicial notice of the information and document, including its terms, appearing on government websites. Supra n.19.

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

Plaintiff's prior effort to rely on the absence of a direct contract between GSK and HRSA is the height of formalism over substance. As an initial matter, as outlined in Apexus's motion, GSK has a contract governing its participation in the Prime Vendor Program with Apexus, which acts on behalf of and pursuant to its contract with HRSA to administer HRSA's program. Beyond that, the existence of a contract is not required for a private entity to be immune under a conduct-based theory of immunity. As the name suggests, it is the conduct, not whether there is a contract, that is relevant. See Name.Space, Inc., 202 F.3d at 581 ("mere status as a government contractor" insufficient to confer conduct-based immunity). Indeed, the court in Byers v. Intuit made this very point when it held that "conformance" to IRS policy was the basis for invoking immunity. Byers, 600 F.3d at 295. To hold otherwise would achieve the absurd result that only Apexus—but not GSK—would be immune for GSK's participation in the Prime Vendor Program. Yet the very purpose of the program, driven by HRSA, directs that drug manufacturers such as GSK provide discounts to covered entities.

For these reasons, as well as those articulated in Apexus's Motion, plaintiff's claims fail and this Court should enter judgment finding that GSK is immune from the complained of conduct.

B. GSK's Sales to SNHD Fall Under the "Own Use" Exemption to the Robinson-Patman Act

Even if GSK's vaccine sales to SNHD were not immune from antitrust scrutiny, plaintiff's claims fail because the challenged sales are statutorily exempt from the Robinson-Patman Act. The Act "makes it unlawful for one engaged in commerce to discriminate in price between different purchasers of like commodities when, among other things, 'the effect of such discrimination may be substantially to lessen competition.'" Abbott Laboratories v. Portland Retail Druggists Assoc., 425 U.S. 1, 3-4 (1976) citing 15 U.S.C. § 13(a). The Nonprofit Institutions Act ("NPIA"), however, establishes that the Robinson-Patman Act does not reach purchases of

supplies to "schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit" that are "for their own use." 15 U.S.C. § 13(c). The purpose of this exemption "was undoubtedly to permit institutions which are not in business for profit to operate as inexpensively as possible." Logan Lanes, Inc. v. Brunswick Corp., 378 F.2d 212, 216 (9th Cir. 1967). To qualify for this exemption: (i) SNHD must fall into one of the categories of eligible institutions and (ii) the vaccines purchased must be for SNHD's "own use." SNHD easily satisfies both criteria.

1. SNHD Qualifies as a "Charitable Institution" Not Operated for Profit

In its opposition to SNHD's motion to dismiss, The Vaccine Center concedes that SNHD qualifies as a non-profit under the NPIA; plaintiff challenges only that SNHD purchased the vaccines for its "own use." (See Docket No. 56, p. 17.) Nevertheless, there is no question that SNHD would otherwise qualify. As the Ninth Circuit has explained, there is little instruction on what qualifies as a "charitable institution" for purposes of the NPIA. De Modena v. Kaiser Foundation Health Plan, Inc., 743 F.2d 1388, 1391 (9th Cir. 1984). The inquiry, here, as it did in De Modena, turns on the meaning of "charitable" institutions. Id. at 1392. Although in the healthcare context the term was first limited to organizations funded by donations, as the landscape of healthcare in this country has changed, the term "charitable" now applies to "all non-profit organizations which promote health." Id. Applying this understanding of "charitable," the Ninth Circuit held that regional Kaiser Health plans—each a health maintenance organization (HMO) that contracted with members to provide health-related services through related organizations in exchange for a monthly fee—qualified as "charitable institutions" for purposes of the NPIA. Id. The U.S. Federal Trade Commission ("FTC") likewise issued an Advisory

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

Opinion holding that a nonprofit Kaiser Health HMO was "charitable" for purposes of the NPIA.[22]

Under the analysis adopted by the Ninth Circuit in De Modena, SNHD must also be considered a charitable institution not operated for profit under the NPIA. SNHD is a public health organization created by Nevada statute. NRS 439.361 et seq. Its mission is to promote and protect "the health, the environment and well-being of Southern Nevada residents and visitors."[23] Empowered with jurisdiction over "all public health matters in the district," it is specifically tasked with regulating "the prevention, suppression, and control of any contagious or infectious disease dangerous to the public health." NRS 439.350(2). It is beyond dispute that these goals are "charitable" in nature. De Modena, 743 F.2d at 1392; see also Sec. & Exch. Comm'n v. Children's Hosp., 214 F. Supp. 883, 889–90 (D. Ariz. 1963) (in context of exemption from Securities Act, a healthcare organization is "not required to furnish free services to the indigent as a condition precedent to a 'charitable' exemption, as long as the hospital is devoted to . . . aiding in maintaining public health").

Indeed, the touchstone of an entity organized for charitable purposes is that any funds it derives are not used for private gain but rather held in trust in furtherance of the goals and maintenance of the organization. Children's Hosp., 214 F. Supp. at 889–90, citing People ex rel. Cannon v. Southern Illinois Hospital Corp., 404 Ill. 66 (1949); Southern Methodist Hospital and Sanatorium of Tucson v. Wilson, 77 P.2d 458, 459 (Ariz. 1938); see also Logan Lanes, 378 F.2d at 216 (considering fact

[22] The FTC issues advisory opinions to "help clarify FTC rules and decisions, often in response to requests from business and industry groups." Federal Trade Commission, Advisory Opinions, available at http://www.ftc.gov/policy/advisory-opinions; see also Federal Trade Commission, Kaiser Foundation Health Plan, Inc., Advisory Opinion, Feb. 13, 2008, available at http://www.ftc.gov/sites/default/files/documents/advisory-opinions/kaiser-foundation-health-plan/080213kaiser.pdf. A true and correct copy is attached hereto as Exhibit 5. GSK requests the Court take judicial notice of the information and document, including its terms, appearing on government websites. Supra n.19.

[23] Southern Nevada Health District, available at http://www.southernnevadahealthdistrict.org/index.php.

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

that net income went to funding student activities or improvement of university in concluding that bowling alleys at issue were not operated for profit). Here, any fees derived from the administration of vaccines[24] are statutorily required to be held in a fund created specifically for the Health District. NRS 439.363. This fund "may only be used to provide funding for the health district." Id. Without doubt, this qualifies SNHD as a "charitable institution not operated for profit" for purposes of the NPIA.

2. The Vaccines Sold by GSK to SNHD Are for SNHD's Own Use

The second inquiry—whether the vaccines were for SNHD's own use—is answered with equal certainty. In Abbott Laboratories, the Supreme Court established the definition of "own use" as use that is "part of and promotes [the entity's] intended institutional operation." Abbott Laboratories, 425 U.S. at 14. In that case, the entity at issue was a nonprofit hospital. The intended institutional function, therefore, was the medical care of hospital patients. Id. Using this as a benchmark, the Court analyzed whether the relevant pharmaceutical products qualified as "own use." Prescription refills, sales to hospital medical staff for subsequent resale, and sales to walk-in customers who were not being treated at the hospital fell beyond the bounds of "own use" by the hospital because they were beyond the bounds of medical care of patients in the hospital, and were therefore not exempt. Id. at 14–15. In contrast, prescriptions used on hospital premises, including during admission to emergency room; by inpatients or outpatients for personal use off hospital premises (not including refills); and to hospital employees and physicians for personal use or use by a dependent were all considered the hospital's "own use." Id. Also, the defendants in Abbott conceded, and the Supreme Court agreed, that "own use" encompasses a patient "***receiving a shot*** or pill while standing upright or

[24] The fees charged by SNHD for vaccines are limited to the cost of the vaccine plus a nominal administrative fee. Sorenson Decl. at ¶ 12.

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

otherwise in the outpatient clinic," see id. at 12 (emphasis added), as well as outpatient use on the hospital premises generally, id. at 9.

Applying Abbott, the Ninth Circuit in De Modena recognized that the Supreme Court's mandate requires identifying the entity's "basic institutional function" and then deciding which sales fit within that function, rather than adopting the categorical scenarios posited in Abbott. De Modena, 743 F.2d at 1393. The Kaiser Heath HMOs had an "extraordinar[il]y broad institution function" of providing a panoply of health care to their members on a continuing and often preventative basis. Id. As a result, the Ninth Circuit concluded that "any sale of drugs by an HMO to one of its members falls within the basic function of the HMO" and, as a result, these sales fell within the own use exemption to the NPIA. Id.; see also, e.g., In re Brand Name Prescription Drugs Antitrust Litig., No. 94-897, 1995 WL 715848 (N.D. Ill. Dec. 4, 1995) (granting summary judgment for defendant because purchases by two HMOs fell within own use exemption to NPIA). The court also recognized that because of its unique, broad institutional function, the Kaiser HMO's "own use" included certain types of sales that, if made by the hospitals in Abbott, might not have been protected. See De Modena, 743 F.2d at 1393 n.7.

The basic institutional function of SNHD is to promote and protect "the health, the environment and well-being of Southern Nevada residents and visitors." One of its statutorily enumerated responsibilities is to regulate "the prevention, suppression, and control of any contagious or infectious disease dangerous to the public health." NRS 439.350(2). It also has the power "[t]o take whatever action that is necessary to control communicable diseases." Clark County Ord., § 3.08.070. None of these clearly articulated goals is limited to a particular segment of the population (*e.g.*, the poor or uninsured). Indeed, the prevention of disease through vaccines requires immunization of as large of a percentage of the population as possible. To achieve herd immunity, improving access—particularly in historically under-vaccinated populations—is key. This is precisely how SNHD uses the vaccines it

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

purchases from GSK. (Sorenson Decl. at ¶¶ 3 and 9–10; SNHD Immunization Project Dosage Report, SNHD004053-SNHD004114, attached as Exhibit 1-B.) During the relevant time period, SNHD offered the vaccines purchased from GSK at its clinic locations and through contracts with local employers. (Sorenson Decl. at ¶¶ 9 and 13–14.) Employees received vaccinations either at their place of business, administered by a SNHD health care worker, or at a SNHD clinic location. (See Sorenson Decl. at ¶ 14; SNHD Workplace Vaccination Records, SNHD004051-SNHD004052, attached as Exhibit 1-C.)

Consistent with its mission, SNHD's services are administered without regard to a person's ability to pay. (Sorenson Decl. at ¶ 3.) SNHD fees are based solely on the cost of the vaccines plus a nominal administrative fee. This is true for both vaccines administered in health district clinics and those done pursuant to contract. (Id. at ¶ 12 and 14.) Any revenue collected is deposited in the health district fund and must—by statute—only be used for the health district itself. NRS 439.363(2). No private individual or entity, nor any officer or director of SNHD, personally benefits from fees collected from the administration of vaccines. (Sorenson Decl. at ¶ 15.)

SNHD's efforts to improve access to important vaccines are particularly critical with regards to the four vaccines identified in plaintiff's Amended Complaint: Boostrix, Engerix, Havrix, and Twinrix (the four vaccines plaintiff has purchased from GSK[25]). The Centers for Disease Control and Prevention ("CDC") recommends all adults receive a Td/Tdap booster every ten years (Boostrix) and that adults who were not vaccinated as children for hepatitis A and hepatitis B and whose health, job, or lifestyle might put them at higher risk for serious disease, receive vaccinations for

[25] See The Vaccine Center Invoices and Purchase Records, TVC_000384-TVC_000405 and TVC_000905-TVC_000911, attached as Exhibit 1-D.

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

those diseases (Engerix, Havrix, Twinrix).[26] These recommendations are entirely separate from any recommendations for vaccines for individuals traveling outside of the United States, which is the focus of plaintiff's business.[27]

Where a vaccine is administered is of no relevance to whether it promotes the health district's mission. Unlike a hospital, which functions to care for patients on its premises, the health district's function of reducing the risk of infectious disease in the community is served ***at least*** equally by a vaccine administered in one of its clinic locations as one administered by a SNHD health care employee at private premises. Facilitating the ease with which the community can obtain immunizations—namely by going to businesses—increases vaccine coverage of the population, and, therefore, furthers the health district's goal of minimizing these dangerous and contagious diseases.

A recent FTC Advisory Opinion emphasizes that geographic location of the "use" off-site does not take the conduct outside of the "own use" exception. Community CarePartners, Inc., a non-profit organization providing post-acute care health services, including hospice services,[28] sought an opinion from the FTC on whether prescription drugs administered to in-home hospice patients qualify under the own use exemption.[29] The FTC concluded that the sale of discounted pharmaceuticals to in-home hospice patients would fall within the own use exemption under the NPIA. In reaching this decision, the FTC found that the goal of

[26] See Centers for Disease Control and Prevention, 2014 Recommended Immunizations for Adults by Age, available at http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule-easy-read.pdf.

[27] Id.

[28] Hospice services focus on providing medical care as well as emotional support and resources for people who are in the last stages of a serious illness.

[29] Federal Trade Commission, Community CarePartners, Inc., Advisory Opinion, July 2, 2010, available at http://www.ftc.gov/sites/default/files/documents/advisory-opinions/community-carepartners-inc./100702carepartnersopinion.pdf. A true and correct copy is attached hereto as Exhibit 6. GSK requests the Court take judicial notice of the information and document, including its terms, appearing on government websites. Supra n.19.

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

CarePartners—to help people "live fully despite injury, illness, disability, or age" and to provide uninterrupted care to those individuals—was undiminished by geographic location. In other words, the place of treatment was irrelevant to an "own use" assessment of the discounted products. The same is true here. SNHD's mission of improving community health and curtailing infectious disease is furthered equally or more strongly with the administration of vaccines outside of SNHD's clinics.

Similarly, whether a vaccination occurs via an individual visiting a SNHD clinic on his own accord or through a contract with a community employer does not change that both uses are fully aligned with achieving SNHD's intended mission of reducing the risk of disease. Again, ensuring that large groups of the population receive immunizations advances that goal more rapidly and efficiently.

The provision of vaccines by SNHD to the community, therefore, falls squarely within "own use" as it is defined by the Supreme Court and the Ninth Circuit. Accordingly, GSK's sales of vaccines to SNHD are exempt from the Robinson-Patman Act.

[*Remainder of Page Intentionally Left Blank*]

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

IV. CONCLUSION

Acting pursuant to the consistently articulated policy and program of the federal government, and with the documented consent of the specific agency responsible for administering that policy, GSK, Apexus, and SNHD are immune from antitrust scrutiny on conduct-based immunity grounds. Even if that were not the case, the vaccines sold to SNHD are exempt on the basis of the "own use" exemption under the Nonprofit Institutions Act because their administration to the community furthers the institutional goal of the health district to improve the health of residents and visitors and to prevent the spread of infectious and communicable disease. Neither of these reasons may be cured by re-pleading. Thus, for each of these separately sufficient reasons, the Court should grant GSK's summary judgment motion and dismiss the complaint with prejudice.

Dated: July 22, 2014

By: /s/ *Edward Chang*

Stanley W. Parry, Esq.
Nevada Bar No. 1417
Edward Chang, Esq.
Nevada Bar No. 11783
BALLARD SPAHR LLP
100 North City Parkway, Suite 1750
Las Vegas, Nevada 89106
Telephone: (702) 471-7000

Stephen J. Kastenberg, Esq.
(admitted pro hac vice)
Jason A. Leckerman, Esq.
(admitted pro hac vice)
Jessica M. Anthony, Esq.
(admitted pro hac vice)
BALLARD SPAHR LLP
1735 Market Street, 51st Floor
Philadelphia, Pennsylvania 19103
Telephone: (215) 665-8500

Attorneys for Defendant GlaxoSmithKline LLC

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

CERTIFICATE OF SERVICE

I certify that on July 22, 2014, and according to Fed. R. Civ. P. 5(b), I served via CM/ECF and/or deposited for mailing in the U. S. Mail a true and correct copy of the foregoing *DEFENDANT GLAXOSMITHKLINE'S MOTION FOR SUMMARY JUDGMENT,* postage prepaid and addressed to all parties as identified on the Court-generated Notice of Electronic Filing.

/s/ *Edward Chang*
An employee of BALLARD SPAHR LLP

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070